

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

) THIS DOCUMENT RELATES TO:)
) SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
) AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9062

Bartle, J.

May 9, 2013

Rhonda Murray ("Ms. Murray" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Jay J. Libys, M.D., F.A.C.C. Based on an echocardiogram dated April 18, 2003, Dr. Libys attested in Part II of Ms. Murray's Green Form that she suffered from severe mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.³ Based on such findings, claimant

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Libys also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition is not at issue in this claim.

would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.⁴

In the report of the claimant's echocardiogram, Dr. Libys stated that claimant had severe mitral regurgitation of more than 41%. Dr. Libys, however, did not specify an exact percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, severe mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is greater than 40% of the Left Atrial Area ("LAA"). See Settlement Agreement §§ I.22 & IV.B.2.c. (2) (b).

In July, 2005, the Trust forwarded the claim for review by Karen H. Hamilton, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Hamilton concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had severe mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. Hamilton explained, "The [mitral regurgitant] jets are small, measuring 13% of [the left atrial] area or less. The sonographer traced a very large area of early systolic blue backflow; that

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c. (2) (b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

area was used as a[mitral regurgitant] jet area leading to the incorrect conclusion about [mitral regurgitation] severity."

Based on Dr. Hamilton's finding that claimant did not have at least moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Murray's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant submitted a letter from Dr. Libys wherein he stated that Ms. Murray had "at least moderate and significant mitral regurgitation." Dr. Libys explained:

I certainly differ from Dr. Karen Hamilton, the auditing cardiologist. The basis of my opinion is that I have taken into consideration the area and extent of turbulent flow. Dr. Hamilton makes no comment of this significant finding, yet the echocardiogram clearly shows mitral regurgitation with turbulent flow going into the pulmonary vein.

I also note that Dr. F. Alan Covin, a board certified cardiologist has also reported his opinion that Mrs. Murray has moderate to severe mitral regurgitation by Doppler with the jet area being greater than 40% in the worst view by tracing. Even if Dr. Hamilton considers the tracings generous, she has apparently overlooked the significant turbulent flow into the Pulmonary veins. Mrs. Murray's mitral regurgitation is at least 20-40%. Please see my report of

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Murray's claim.

11/18/04 finding greater than 41%, indicating severe mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Murray's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO NO. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Murray's claim should be paid. On January 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5953 (Jan. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 11, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had at least moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Murray argues that there is a reasonable medical basis for finding that she had at least moderate mitral regurgitation because two board certified cardiologists have interpreted her mitral regurgitation as severe. In addition, claimant submitted an opinion of Lawrence Leader, D.O., F.A.C.C., who concluded that "[t]here is moderate insufficiency noted with a jet that hits the posterior wall and wraps around slightly with estimated regurgitant jet going approximately 25 to 30% of the left atrium." Dr. Leader also observed, "The technician on this study did define an area

greater than that percentage; however, she included an area that did not appear to be regurgitant and took an area slightly further in the cycle than I would normally estimate the jet to be occurring."

In response, the Trust argues that claimant's physicians do not establish a reasonable medical basis for the finding of Dr. Libys. Those physicians do not address Dr. Hamilton's specific observation that Ms. Murray's mitral regurgitant jet was improperly traced. According to the Trust, neither Dr. Libys nor Dr. Leader "identif[ied] a high-velocity, sustained jet of mitral regurgitation seen in multiple consecutive frames and repeated cycles that occupies at least 20% of the representative left atrial area."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's representation that claimant had severe mitral regurgitation. Specifically, Dr. Abramson stated:

In reviewing the transthoracic echocardiogram from 4/18/03, my visual estimate is that there is only mild mitral regurgitation in all views. Both of the [mitral regurgitant] jet areas on the tape are over traced and include significant amounts of non-regurgitant flow. The left atrial area on the tape is under traced and is only measured once. Both the [mitral regurgitant] jet and the [left atrial] area are larger on the apical-2-chamber view so it is important to measure them in the same view. I re-measured the two jets (previously measured on the tape) and a third one that was representative of the jets viewed on the echocardiogram. My

measurements for these three jet areas/left atrial areas are $2.9 \text{ cm}^2/19.0 \text{ cm}^2$, $4.0 \text{ cm}^2/25.7 \text{ cm}^2$, and $3.5 \text{ cm}^2/21.3 \text{ cm}^2$. These ratios are 15%, 16% and 16%, all of which are less than 20%, and are consistent with mild mitral regurgitation.

In response to the Technical Advisor report, claimant argues that inter-reader variability could account for the difference between the conclusions of her cardiologists and Dr. Hamilton and Dr. Abramson. Ms. Murray further asserts that Dr. Abramson should also have been asked to address whether there was a reasonable medical basis for finding moderate mitral regurgitation in addition to being asked about severe mitral regurgitation. Claimant also contends that Dr. Covin, who performed claimant's echocardiogram through the Trust's Screening Program,⁷ opined that Ms. Murray had severe mitral regurgitation. Finally, Ms. Murray argues that Dr. Libys does specifically address Dr. Hamilton's opinion that the sonographer over traced her mitral regurgitant jet and that Dr. Leader refers to a jet of moderate mitral regurgitation "that hits the posterior wall and wraps around slightly."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, the opinions of Dr. Libys and Dr. Leader do not provide a reasonable medical basis for the representation of Dr. Libys that claimant had at least moderate mitral regurgitation. As we

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

previously have explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow," and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Hamilton observed that the "sonographer traced a very large area of early systolic blue backflow; that area was used as a[mitral regurgitant] jet area leading to the incorrect conclusion about [mitral regurgitation] severity." Similarly, Dr. Abramson concluded that "[b]oth of the [mitral regurgitant] jet areas on the tape are over traced and include significant amounts of non-regurgitant flow." Dr. Abramson also noted that "[t]he left atrial area on the tape is under traced and is only measured once." Although Dr. Leader acknowledged the deficiencies identified by Dr. Hamilton, he estimated that claimant's RJA/LAA ratio was between 25% and 30%. Dr. Abramson, however, measured claimant's RJA and LAA and determined that Ms. Murray's RJA/LAA ratio was between 15% and

16%, consistent with mild mitral regurgitation.⁸ Such unacceptable practices on the part of claimant's physician cannot provide a reasonable medical basis for the resulting Green Form representation of at least moderate mitral regurgitation.

Moreover, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had at least moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist determined that claimant's echocardiogram demonstrated only mild mitral regurgitation and the Technical Advisor determined claimant's echocardiogram demonstrated an RJA/LAA ratio of between 15% and 16%. Adopting claimant's argument would allow a claimant to recover benefits with an RJA/LAA ratio below the threshold established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.⁹

8. For this reason as well, we reject claimant's argument that the Technical Advisor's opinion is entitled to less weight because Dr. Abramson was not specifically asked to address whether claimant had moderate mitral regurgitation.

9. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement, "Even taking into account inter-reader variability, Rhonda Murray has mild mitral regurgitation."

Finally, to the extent claimant asserts that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of the claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement, such argument is misplaced. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662

(Nov. 26, 2002), which mandates a 100% audit requirement for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had at least moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Murray's claim for Matrix Benefits.